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Proposed Registration Decision PRD2012-24

Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides

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Overview

Proposed Registration Decision for Clothianidin Insecticide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing a renewal of the conditional registration for the sale and use of Clothianidin Technical Insecticide, Clutch 50 WDG Insecticide, Arena 50 WDG Insecticide and Clothianidin Insecticide, containing the technical grade active ingredient clothianidin, to control a variety of insects on potato, grape, pome fruits, stone fruits and turf.

Clothianidin Technical Insecticide (Registration Number 27445), Clothianidin Insecticide (Registration Number 29381), Clutch 50 WDG Insecticide (Registration Number 29382) and Arena 50 WDG Insecticide (Registration Number 29383) were granted conditional registration in Canada in 2009. The detailed review for Clothianidin Technical Insecticide, Clothianidin Insecticide, Clutch 50 WDG Insecticide, and Arena 50 WDG Insecticide can be found in the Evaluation Report ERC2011-01, *Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides*. The original evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk reduction measures are followed, as a condition of the original registrations, additional scientific information was requested from the applicant to be submitted by December 2012. In support of the request to renew the conditional registrations, a rationale for renewal of the registration in the absence of required data or information was provided. Based on a review of the submitted rationale, the Agency proposes a renewal of the conditional registration for Clothianidin Technical Insecticide, Clutch 50 WDG Insecticide, Arena 50 WDG Insecticide and Clothianidin Insecticide. The requirement to submit additional scientific information as a condition of registration remains.

This Overview describes the key points of the original evaluation, while the Science Evaluation of Evaluation Report ERC2011-01, *Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides* provides detailed technical information on the human health, environmental and value assessments of Clothianidin Technical Insecticide, Clothianidin Insecticide, Clutch 50 WDG Insecticide and Arena 50 WDG Insecticide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on clothianidin, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on clothianidin, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of Evaluation Report ERC2011-01, *Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides*.

What Is Clothianidin?

Clothianidin is the active ingredient contained in Clothianidin Technical Insecticide, Clutch 50 WDG Insecticide, Arena 50 WDG Insecticide and Clothianidin Insecticide. It is an agricultural insecticide that can be applied to the foliage of plants or in-furrow to control a variety of important insect pests in several crops and turf. Clothianidin is a member of the neonicotinoid group of insecticides.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of Clothianidin Affect Human Health?

Clothianidin is unlikely to affect your health when used according to label directions.

Exposure to clothianidin may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when clothianidin products are used according to label directions.

The technical grade active ingredient clothianidin was highly acutely toxic to mice when ingested. Consequently, the statement "Danger Poison" was required on the label for the technical grade active ingredient.

Clothianidin did not cause cancer in laboratory animals and is non-genotoxic. The first signs of toxicity in animals given daily doses of clothianidin over longer periods of time were decreased food consumption, body weights, and body weight gains. Target organs of toxicity included the liver, kidney and reproductive organs, as well as the gastrointestinal tract and immune system.

Clothianidin did not cause birth defects in laboratory animals. There was evidence in animals that the young are more sensitive to the effects of clothianidin than adults. Effects on the young were observed at doses lower than those that caused effects in parental animals. In addition, signs of neurotoxicity were also seen in young animals at dose levels lower than those given to parental animals. Because of these observations, extra protective factors were applied during the risk assessment to further reduce the allowable level of human exposure to clothianidin.

The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The aggregate refined chronic dietary intake estimates (food plus water) revealed that infants, the subpopulation which would ingest the most clothianidin relative to body weight, are expected to be exposed to less than 66% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from exposure to clothianidin residues is not of concern for any of the population sub-groups.

A single dose of clothianidin is not likely to cause acute health effects in the general population (including infants and children). An aggregate (food and water) dietary exposure estimate of 31% of the acute reference dose is not considered to be a health concern for any of the population sub-groups.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Crop field trials conducted in North American Free Trade Agreement (NAFTA) geographical representative regions using the end-use product containing clothianidin in/on grapes, pome fruits, and stone fruits were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of Evaluation Report ERC2011-01, *Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides*.

Risks in Residential and Other Non-Occupational Environments

Exposure to the public in treated turfgrass areas, and treated orchard areas is considered acceptable when clothianidin-containing products are used according to label directions.

Exposure of the general population to residues of clothianidin could occur from entering treated residential and municipal turf areas. The postapplication exposure to adults, youths, and children were considered acceptable.

Exposure of the general population to residues of clothianidin from treated orchards could occur by participating in pick-your-own (U-pick) activities for apple, pear, peaches, nectarines, sweet or sour cherries, and plums. The exposures from such activities are considered acceptable for adults, youths, and children.

Occupational Risks from Handling Arena 50 WDG Insecticide, Clutch 50 WDG Insecticide and Clothianidin Insecticide

Occupational risks are not of concern when the end-use products are used according to the label directions, which include protective measures.

Farmers, custom applicators, or professional lawn care operators who mix, load or apply Arena 50 WDG Insecticide, Clutch 50 WDG Insecticide, or Clothianidin Insecticide, as well as field workers re-entering freshly treated turf (including sod farm, golf course, residential, municipal, and industrial sites), crop fields, orchards and vineyards, can come in direct dermal contact with clothianidin residues. Therefore, the label specifies that anyone mixing/loading and applying Arena 50 WDG Insecticide, Clutch 50 WDG Insecticide and Clothianidin Insecticide must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes; and, for aerial application, additional protective equipment of coverall, and goggles or faceshield. The label also requires that workers do not enter treated fields for 12 hours after application. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to these individuals is not a concern.

For bystanders, exposure is expected to be much less than that for workers and is not quantified. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Clothianidin Is Introduced Into the Environment?

Clothianidin is largely stable in the environment and could leach to groundwater in certain types of soils. It will, however, not evaporate from soil or water. Field dissipation studies confirm clothianidin's persistence and, in spite of the predictions for high mobility from laboratory studies, they show that a fraction of the applied active ingredient can remain in the top soil layers. Clothianidin is a systemic pesticide and can be absorbed from soil and transferred by plants into pollen and nectar.

Clothianidin is highly toxic to bees and mammals and moderately toxic to birds. In water, it is very highly toxic to aquatic invertebrates, but only slightly toxic to fish.

Because clothianidin is systemic, persistent and highly toxic to honey bees, the PMRA has requested additional data to fully assess the potential effects of chronic exposure of this pesticide, resulting from its potential movement into plant tissues and secretions such as pollen and nectar.

Additionally, the PMRA has initiated a re-evaluation of clothianidin and the other nitro-guanidine neonicotinoid insecticides (Re-evaluation Note REV2012-02, *Re-evaluation of Neonicotinoid Insecticides*) that will focus on potential effects on pollinators and will include consideration of all new scientific evidence. The PMRA is working with the United States Environmental Protection Agency (USEPA) and other international regulatory partners to develop additional data requirements and enhanced risk assessment methods and to develop and implement risk mitigation measures in a timely manner. Should evidence become available demonstrating reasonable grounds to believe that health or environmental risks of clothianidin are unacceptable, the PMRA will take appropriate regulatory action.

Value Considerations

What Is the Value of Clutch 50 WDG Insecticide, Arena 50 WDG Insecticide and Clothianidin Insecticide?

These end-use products control a variety of important insect pests on turfgrass, potatoes, grapes and pome and stone fruits.

Sufficient efficacy data were provided to support the three products for the control of a variety of insect pests in potato, pome fruit, stone fruit, grapes and turf. The efficacy data confirmed the lowest effective rate for major pests and the data supported the rates for additional pests. The data support multiple methods of application including in-furrow on potato, foliar on potato, pome fruit, stone fruit, grapes and turf, and aerial application on potatoes.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of Arena 50 WDG Insecticide, Clutch 50 WDG Insecticide or Clothianidin Insecticide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Anyone mixing, loading and applying the end-use products must wear a long-sleeved shirt, long pants, chemical-resistant gloves, and socks and shoes. Aerial applicators must also wear coveralls and goggles or faceshield. No human flaggers are permitted. In addition, precautionary measures are required to protect against drift during application. A 12-hour restricted-entry interval is required for all occupational postapplication tasks. There is no public access to treated areas until sprays have dried.

Environment

Hazard statements are required for toxicity to aquatic organisms, wild mammals, bees and other beneficial insects with associated precautionary measures. Buffer zones are required to mitigate the risk to aquatic organisms. Precautionary measures are also required to address concerns related to carryover, runoff and leaching.

What Additional Scientific Information Is Being Requested?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of Evaluation Report ERC2011-01, *Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides* or in the section 12 Notice associated with the renewal of these conditional registrations. The applicant must submit the following information by December 2015.

Environment

- A lysimeter study conducted in coarse textured soil with a water dispersible granule (WDG) formulation.
- A study of behaviour and fate of clothianidin in plants, including determination of concentrations in nectar and pollen.
- A hive study designed to assess the chronic toxicity of clothianidin to bees.

Next Steps

Before making a final registration decision on the applications to renew the conditional registration for Clothianidin Technical Insecticide, Clutch 50 WDG Insecticide, Arena 50 WDG Insecticide and Clothianidin Insecticide, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on clothianidin (based on the Science Evaluation of Evaluation Report ERC2011-01, *Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides*). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).